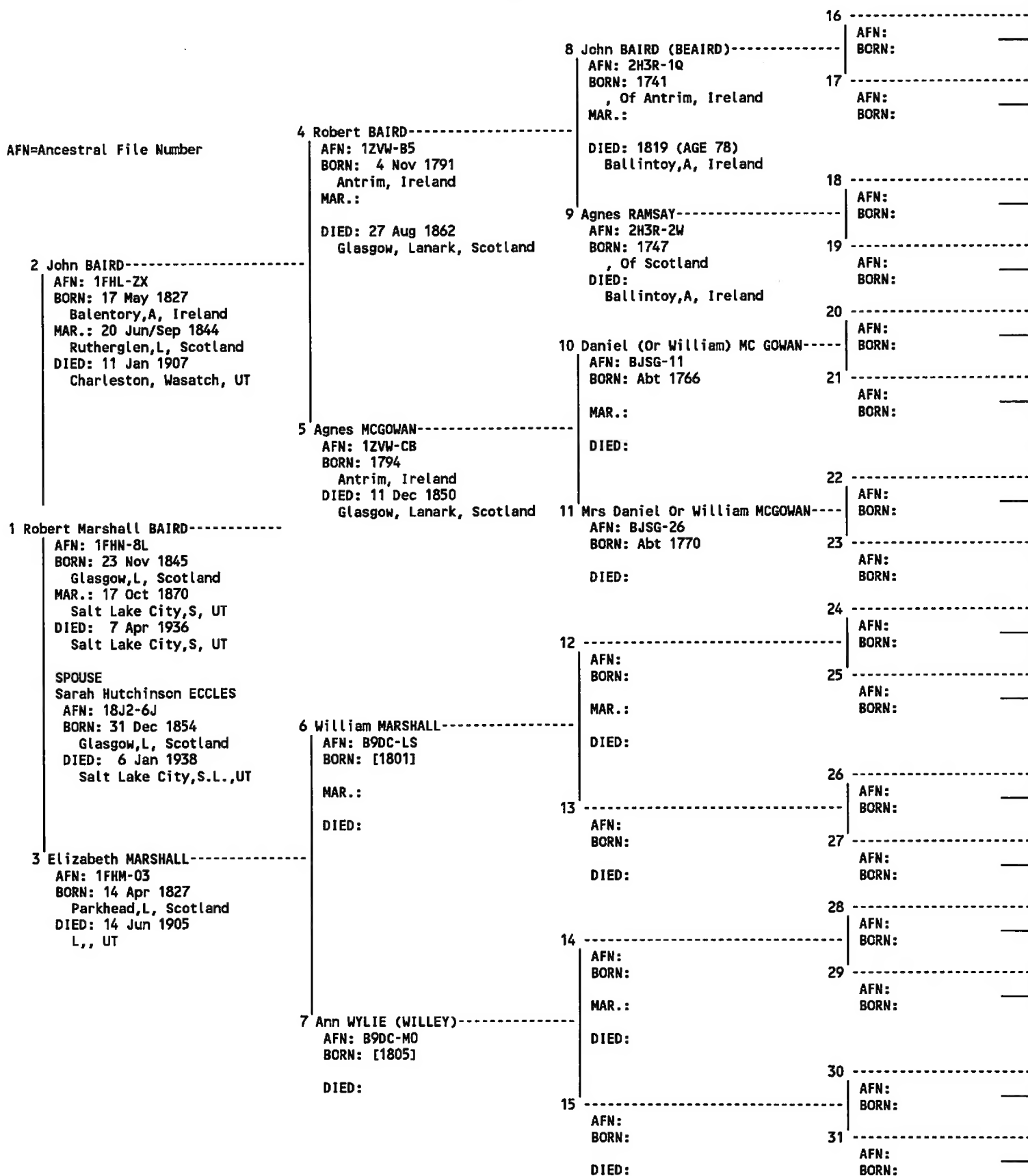


No. 1 on this chart is the same as no. _____ on chart no. _____

AFN=Ancestral File Number



John Baird

Indications and Administration Guidelines for I.V. Conscious Sedation

is a potent sedative agent which requires slow administration and individualization of dosage. Clinical experience has shown that VERSED is 4 times as potent per mg as diazepam. SERIOUS AND LIFE-THREATENING CARDIORESPIRATORY ADVERSE EVENTS HAVE BEEN REPORTED. PROVISIONAL MONITORING, DETECTION AND CORRECTION OF THESE EVENTS MUST BE MADE FOR EVERY PATIENT TO WHOM VERSED INJECTION IS ADMINISTERED, REGARDLESS OF AGE OR CLINICAL STATUS. Excess doses or rapid or single bolus intravenous administration may result in respiratory depression and/or arrest.

Considerations

VERSED must be individualized and titrated; never give by rapid or bolus. VERSED 1 mg/mL is recommended to facilitate slower titration. Both the 1 mg/mL and 5 mg/mL formulations may be diluted in sodium chloride or 5% dextrose in water. Individual patient response will vary with age, physical status and concurrent medications, but may also vary independent of these factors. Narcotic premedication results in less variability in patient response and a reduction in dosage of VERSED. For peroral procedures, topical anesthetic is recommended; for bronchoscopies, premedication is recommended. Be aware of the danger of underventilation or apnea is greater in elderly patients and those with chronic disease states or decreased pulmonary reserve. Because the peak effect may take longer in these patients, the dose should be smaller and the rate of injection slower.

Titrate slowly to the desired effect, i.e., initiation of slurred speech. Most patients may respond to as little as 1 mg.

Adults Under 60:	Debililitated or Chronically Ill Patients; Patients 60 or Older: Unpremedicated
Initial Titration: Administer 2.5 mg. Administer over at least 2 minutes.	Initial Titration: Not to exceed 1.5 mg. Administer over at least 2 minutes.
Increments: Wait an additional 2 minutes to evaluate effect. Administering with small increments.	Increments: Wait an additional 2 minutes to evaluate effect. No more than 1 mg over a 2-minute period.
Wait at least 2 minutes after each increment to evaluate effect.	Wait at least 2 minutes after each increment to evaluate effect.
Do not administer more than 5 mg.	Total Dose: Usually, no more than 3.5 mg.
Adults Under 60:	Debililitated or Chronically Ill Patients; Patients 60 or Older: Premedicated (narcotic or other CNS depressants)
Reduced Dose for other CNS depressants: Patients require 30% less than an unpremedicated patient.	Patients require at least 50% less VERSED than healthy, young unpremedicated patients.

If a thorough clinical evaluation indicates need for additional sedation, administer, by slow titration, 25% of dose used to first reach desired point.

